

REMARKS

A. Status of the Claims

Claims 1-36 and 67-108 were pending at the time of the November 2003 Office Action. Claim 69 has been amended. No claims have been added or deleted. Thus, claims 1-36 and 67-108 will remain pending upon entry of the requested amendment.

B. Examiner Interview

Applicants thank Examiner Thaler for granting Applicants a courteous personal interview with their representative Mark Garrett, along with András Kónya and Jeffery Sheldon on February 6, 2004. The claims of record and cited prior art were discussed. Applicants demonstrated a prior art stent—the WALLSTENT®—and a stent created according to the claims, and Examiner Thaler examined them. The propriety of the asserted combination of the Wallsten and Sandock patents was discussed. The Examiner reserved judgment on the patentability of the claims.

C. The Rejected Claims Are Patentable over Wallsten and Sandock

The Office rejects claims 1-16, 18-27, 29-33, 35, 36, 67-86, 88-105, 107 and 108 as being obvious over the asserted combination of U.S. Patent No. 4,655,771 to Wallsten (Wallsten) in view of U.S. Patent No. 5,800,519 to Sandock (Sandock). Applicants respectfully traverse.

1. Request for Clarification

The Office specifically addresses claims 1, 2, 5, 8, 9, 12-16, 69, and 70 in the Action. The Office lists claims 3, 4, 6, 7, 10, 11, 18-27, 29-33, 35, 36, 71-86, 88-105, 107 and 108 among those it is rejecting, and states that the rejection is based on the Wallsten-Sandock combination, but does not explain how those references apply. Applicants submit that more is needed to establish a proper rejection of claims 3, 4, 6, 7, 10, 11, 18-27, 29-33, 35, 36, 71-86, 88-

105, 107 and 108. *See* M.P.E.P. § 707.07(d) (“Where a claim is refused for any reason relating to the merits thereof it should be ‘rejected’ and the ground of rejection **fully and clearly stated** A plurality of claims should never be grouped together in a common rejection, unless that rejection is equally applicable to all claims in the group.”) (emphasis added); 37 C.F.R. § 104(c)(2). Applicants respectfully request that the Office explain how the Wallsten-Sandock combination applies to these claims if the rejection of any of them is maintained.

2. Claim 1 and Its Dependents

Claim 1 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having first and second ends, the shape memory wires crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides, and both ends of at least one shape memory wire being located proximate one end of the body; wherein the value of the at least one obtuse angle may be increased by axially compressing the body.

The Office has not established a *prima facie* case of obviousness of claim 1 because it has not identified an appropriate motivation for combining Sandock with Wallsten. Wallsten discloses severing a long string of woven material to create a stent. Col. 3, lines 33-35. The different thread elements of the stent are described as distinct elements that have opposing directions of winding. Col. 4, line 63 – col. 5, line 6.¹ The Office recognizes that “Wallsten fails

¹ Wallsten states, “[t]he alternative in which no free ends at all are present is the alternative to make the tubular body as a whole of one coherent element[,]” but does not provide further information about how to accomplish such a formation, or discuss it further in the patent. Col. 3, lines 30-33.

to disclose both ends of at least one shape memory wire being located proximate one end of the body.” Office Action at page 2. However, the Office asserts:

Sandock teaches that helical wires 11 of a stent should be arranged such that both ends of each wire are located at one end 19 of the body while the wire at the other end 18 of the body is formed into a bend rather than a free end (col. 5, lines 22-55). This arrangement has the apparent advantage of reducing the number of free ends on the wires, which free ends could damage the blood vessel during stent insertion.

Id. at pages 2-3. Sandock specifically states:

Referring now to FIGS. 5 and 5a, a method for making the medical prosthesis is illustrated. A forming mandrel 40 is chosen based on the desired diameter of the prosthesis. The mandrel 40 includes anchoring pins 44, 42 (extending radially about 1 mm) on its outer surface of the mandrel in a pattern that determines the geometric cell pattern. Strands 11 are bent around the top portion 46 of each top anchoring pin 44 to form the distal end 18 of the prosthesis. The strands 11 are then pulled diagonally downward to an adjacent anchoring pin 42 where they are joined. The strands 11 are helically wrapped about each other to form the interlocking joint 13, with each strand passing through a single 360 degree rotation. The two strands 11 are pulled taught so that the interlocking joint 13 rests firmly against the bottom portion 48 of anchoring pin 42 such that each strand is maintained in tension. The free ends of the strands are then pulled downward to the next diagonally adjacent anchoring pin 42. This process is continued until the desired length of the medical prosthesis is achieved.

Col. 5, lines 21-39. Thus, Sandock achieves a body having both ends of a shape memory wire located proximate one end of the body by bending strands 11 around the top portions of top anchoring pins 44 to form the distal end 18 of the body, and then pulling the strands taught and arranging them as described down the mandrel to create interlocking joints 13.

The Office asserts that “[i]t would have been obvious to locate both ends of each Wallsten wire at one end of the body and provide a bend in the wire at the opposite end of the body so that it too would have [the apparent advantage of reducing the number of free ends on the wires, which free ends could damage the blood vessel during stent insertion.]” Office Action at page 3.

The Office has not established a *prima facie* case of obviousness because it has not identified an appropriate motivation for applying Sandock's teaching of bending strands around the top portions of pins and then weaving those bent strands in the manner disclosed in Wallsten. Sandock couples the bent strands with an arrangement that produces interlocking joints 13 and cells with greater than only 4 sides. The bent portions are not disclosed as the solution to any free wire ends problem. Instead, they exist in order to allow for the creation of the special interlocking joints 13; *see* FIG. 5 and col. 5, lines 26-39, which are the critical feature of Sandock's stents. *See* col. 3, lines 15-23 ("Interlocking joints, preferably arranged with joint axes extended in circumferential fashion, maintain the cell structure at all levels of expansion and compression. ... The joints are highly resistant to failure by shear forces, even when repeatedly compressed and expanded."); *see also* the emphasis in the claims on the interlocking joints. The bent portions disclosed in Sandock are merely incident to Sandock's interlocking joints. In contrast, there are no interlocking joints in Wallsten; those stents are created with plain weaving. *See* Wallsten FIG. 1a.

The Office has divorced a discrete aspect of Sandock's disclosed strand arrangement – an aspect that is incident to the creation of the more important interlocking joints – and asserted that one of ordinary skill in the art would have been motivated to use that discrete aspect as the first part of the weaving process disclosed in Wallsten. This amounts to an improper hindsight reconstruction of the subject matter of claim 1.

Even assuming it were proper to pick and choose among the disclosed features of Wallsten and Sandock in this fashion, there still is no reason for one of ordinary skill in the art to look beyond Wallsten to Sandock. The Wallsten patent identifies the free wire end problem raised by the Office, and solves it. *See* col. 3, lines 29-30 ("The free ends of the thread elements

of the tubular body can be modified or protected in several ways.”). Specifically, Wallsten provides 4 different solutions to free wire ends in column 3, lines 29-51:

- “make the tubular body as a whole of one coherent element”;
- attach U-shaped members pair-wise to the ends of nearby wires;
- weld together crossing points of the wires in a ring around the device, severing the string of woven material just outside the welded locations creating the ring, and folding inwardly any ends that extend beyond the ring; and
- bending the free ends of the elements to form loops.

By providing these solutions, Wallsten solves the problem identified by the Office. As a result, there is no logical reason to look to Sandock. Thus, there is no motivation for the combination. *See In re Laskowski*, 871 F.2d 115, 117, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989) (explaining need for reason to make asserted combination).

For all of these reasons, claim 1 and its dependent claims that have been rejected are patentable over the asserted combination of Wallsten and Sandock. Applicants request that the rejection of these claims be withdrawn.

3. Claim 20 and Its Dependents

Claim 20 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having a first end, a second end and being defined by at least n shape memory wires, wherein n is greater than one, the n shape memory wires being arranged such that the body comprises a first portion, the first portion comprising a first woven portion and at least one strut, the shape memory wires of the first woven portion crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides, and both ends of at least one shape memory wire being located proximate one end of the body; wherein the value of the at least one obtuse angle may be increased by axially compressing the body. The Office does not explicitly explain

how the asserted Wallsten-Sandock combination applies to claim 20 and its rejected dependent claims.

Wallsten fails to disclose or suggest a stent having the claimed “at least one strut.” While Sandock discloses interlocking joints 13, there is no motivation for combining such joints with the woven cells of Wallsten. The stents in Wallsten are woven using a plain weave that can be accomplished quickly. Applicants submit that intermingling the interlocking joints of Sandock with Wallsten’s plain weave would upset the efficiency of the process and slow it down. Thus, there is no motivation for such a combination. Furthermore, for the reasons given above, there is no motivation for combining Sandock’s disclosure with Wallsten’s to achieve the claimed “both ends of at least one shape memory wire being located proximate one end of the body[.]”

For all of these reasons, claim 20 and its dependent claims that have been rejected are patentable over what appears to be the asserted combination of Wallsten and Sandock. Applicants request that the rejection of these claims be withdrawn.

4. Claim 67

Claim 67 is directed to an occluding system comprising a plurality of shape memory wires woven together to form a body useful for occluding an anatomical structure, the body having first and second ends, both ends of at least one shape memory wire being located proximate one end of the body, the shape memory wires crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, and at least one of the cells being defined by only four sides; wherein the value of the at least one obtuse angle may be increased by axially compressing the body. The Office does not explicitly explain how the asserted Wallsten-Sandock combination applies to claim 67.

This claim is patentable for at least the same reasons as claim 1. Accordingly, Applicants request that the rejection of this claim be withdrawn.

5. Claim 68

Claim 68 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having an axis, a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the shape memory wire located proximate one end of the body, the first segment extending helically in a first direction around the axis toward the other end of the body, the second segment extending helically in a second direction around the axis toward the other end of the body, the first and second segments crossing each other in a plurality of locations, and the first and second segments alternating being farther from the axis at each location. The Office does not explicitly explain how the asserted Wallsten-Sandock combination applies to claim 68.

Neither Wallsten nor Sandock disclose or suggest a shape memory wire having a first segment and a second segment that are separated by a bend located proximate one end of the claimed body, the first segment extending helically in a first direction around the axis toward the other end of the body, the second segment extending helically in a second direction around the axis toward the other end of the body, the first and second segments crossing each other in a plurality of locations, and the first and second segments alternating being farther from the axis at each location. Accordingly, this claim is patentable over the asserted combination, and the rejection should be withdrawn.

6. Claim 71 and Its Dependents

Claim 71 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, and an intersection of two shape memory wires crossed in non-interlocking fashion; where both ends of at least one shape memory wire are located proximate one end of the body, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

Like claim 1, this claim recites that both ends of at least one shape memory wire are located proximate one end of the claimed body. Wallsten, as the Office concedes, does not disclose this. Furthermore, the asserted combination of Wallsten and Sandock is not proper for the reasons give above with respect to claim 1. The same is all the more clear considering that claim 71 recites an intersection of two shape memory wires crossed in **non-interlocking** fashion; in contrast, interlocking joints 13 are the focus of Sandock. Accordingly, claim 71 and its rejected dependents are patentable over that combination, and the rejection should be withdrawn.

7. Claim 90 and Its Dependents

Claim 90 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, a middle, and an intersection of two shape memory wires crossed in non-interlocking fashion; where both ends of at least one shape memory wire are located nearer one end of the body than the middle, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

Wallsten fails to disclose or suggest the claimed “both ends of at least one shape memory wire [being] located nearer one end of the body than the middle[.]” It is improper to combine

Sandock with Wallsten to remedy this defect in Wallsten for the reasons given above with respect to claim 1. The same is all the more clear considering that claim 90 recites an intersection of two shape memory wires crossed in **non-interlocking** fashion; in contrast, interlocking joints 13 are the focus of Sandock. Accordingly, claim 90 and its rejected dependents are patentable over the asserted Wallsten-Sandock combination, and the rejection should be withdrawn.

D. Claims 69 and 70 Are Patentable Over Hansen

1. Claim 69

Claim 69 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the first segment and second segments being arranged to form loops and twisted segments such that at least two contiguous substantially closed loops are separated from another loop by a twisted segment. The underlined portion has been added to distinguish Hansen.

Hansen fails to disclose or suggest the claimed at least two contiguous substantially closed loops being separated from another loop by a twisted segment. Accordingly, the rejection should be withdrawn.

2. Claim 70

Claim 70 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having two ends and comprising a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the segments being secured to each other in loop-defining

locations, the segments also extending between the loop-defining locations in spaced relation to each other so as to form at least two loops, at least one of the at least two loops having a compressed shape.

The Office asserts that “segments 10 [and] 11” of Hansen extend between loop-defining locations in spaced relation to each other so as to form two loops. More specifically, the Office asserts that “the loops formed by segments 10, 11 helically wind[] around the longitudinal axis of the stent[.]” Office Action at page 5. The Office asserts that the loop-defining locations are, e.g., “in figure 3, where the segments are twisted about each other just below eyelet 13 and where they are twisted about each other at 12[.]” Applicants submit that it is not clear from Hansen FIG. 3 (or any other figure) that filaments 10 and 11 of Hansen do, in fact, helically wind around the stent in a manner that forms at least 2 loops. FIG. 5, which is the only complete stent shown in Hansen, does not appear to clearly show this, nor is there a suggestion in Hansen that the same would be desirable. Accordingly, Applicants submit that the Office has not established a *prima facie* case of obviousness, and request that the rejection be withdrawn.

E. Petition for Extension of Time

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of three months up to and including May 21, 2004 in which to respond to the final Office Action mailed November 21, 2003. The Commissioner is authorized to deduct fee for this extension of time, along with any additional fees under 37 C.F.R. §§ 1.16 to 1.21 required for any reason relating to the enclosed materials, from Fulbright & Jaworski Deposit Account No.: 50-1212/UTKO:002US/MTG.

F. Conclusion

Applicants respectfully submit that claims 1-36 and 67-18 are in condition for allowance.

Should Examiner Thaler have any questions concerning this application, he is invited to contact the undersigned attorney at (512) 536-3031.

Respectfully submitted,



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